Topics Covered

SECTION A:
Microorganisms and their Control in Leather Industry

1. Microorganism problems in leather production
2. Best practices in control of microorganisms
3. Importance of monitoring

SECTION B:
Government Regulations & Market Requirements

1. Risk assessment
2. Government regulations on biocides
3. Market restrictions on biocides

SECTION C:
Questions and General Discussion
SECTION B:

Government Regulations & Market Requirements

1. RISK ASSESSMENT
**Definitions - Hazard & Risk**

**Hazard** is the **intrinsic** capacity to produce an adverse effect

**Risk** is the probability of an exposure to a hazard and the likely outcome of that exposure

**TOXICITY**: Relative capacity of a substance (chemical) to produce harm to living things; it is an inherent property of all chemical substances
Basic Risk Assessment Elements

- **Toxicity**: Inherent toxicity of the chemical
- **Quantity**: How much of the chemical is present
- **Exposure Level**: How much contact with the chemical

RISK is a function of Hazard and Exposure (Potency + Level)
Assessing Risk – Key Concepts

Dose-Response

Route of Exposure
Human Exposure
- Dermal
- Inhalation
- Ingestion
- Eyes

Duration & Timing

Environmental Release

- Land
- Air
- Water
Risk Assessment Process

Hazard Identification
- Hazard Testing / Endpoints:
  - Development toxicity
  - Reproductive toxicity
  - Neurotoxicity
  - Carcinogen
  - Skin Irritation / Corrosivity / Sensitization
  - Eye Irritation / Corrosivity
  - Respiratory sensitization
  - Endocrine effects
- Intensity, frequency, duration
  - Acute tests
  - Sub chronic / chronic

Dose-Response Assessment

Exposure Assessment
- Chemical, physical effects
- Ecological impacts
- Environmental Fate
- Bio-concentration
- Life Cycle assessment
- Weight of evidence; level of confidence
- Uncertainty & extrapolation
- Epidemiology
- Occupational vs consumer exposures
- Cost Benefit Analysis
- Sex & Politics

Risk Characterization
Risk Categorization & Management

Hazard Classes
- Corrosive to skin
- Cancer
- Endocrine disruptor
- Aquatic toxicity

Hazard Categories
- Category 1 – 5 based on standardized testing e.g. Acute Tox Cat. 3

Exposure
- How much contact, what, who, when, where, how?

“There are no poisons, only poisonous doses...”
Paracelsus (1493-1541)
All biocides are hazardous substances ... they need to be, as they are required to control living things.

**Perception:**

"Less is more"
- It is more sustainable to use less biocide

"Greener is cleaner"
- It is more sustainable to use a biocide with a lower hazard categorization

**Reality:**

"Use the RIGHT amount of biocide to adequately control growth"
- Uncontrolled microorganism growth causes financial damage and potential worker health problems

"Use a product that is risk-assessed & registered for the application"
- It is typical that biocides with a less hazardous profile need to be applied in much larger quantities to achieve control
SECTION B:

Government Regulations & Market Requirements

2. GOVERNMENT REGULATIONS ON BIOCIDES
Government Regulations

Many Laws & Regulations apply globally. For example:

- **USA EPA**: TSCA, FIFRA, CPSC, Proposition 65 etc.
  - Laws & Executive orders - federal, state, & county
- **Europe ECHA**: REACh, BPR, Directives, BfR, etc.
  - Regulations, Directives, National laws
- **China MEP**: Complex regulations, GB standards
- **Japan**: CSCL, ISHL, Law 112 – formaldehyde, etc.
- **Many others**…

EPA = Environmental Protection Agency  
TSCA = Toxic Substances Control Act  
FIFRA = Federal Insecticide, Fungicide, Rodenticide Act  
CPSC = Consumer Product Safety Commission  
ECHA = European Chemical Agency  
BPR = Biocidal Products Regulation  
Bfr = Federal Institute for Risk Assessment  
REAC = Registration, Evaluation, Authorization & Restriction of Chemicals  
MEP = Ministry of Environmental Protection  
CSCL = Chemical Substances Control Law  
ISHL = Industrial Safety & Health Law
Regulatory Affairs “Jungle”
Biocidal Products Directive BPD 98/8/EC

Entry into force: 14th of May 2000

Article 1: Scope
1. This Directive concerns:
   (a) the authorisation and the placing on the market for use of biocidal products within the Member States

Goal:
✓ To harmonise the European market for biocidal products and their active substances
✓ To provide a high level of protection for humans and the environment through risk assessment
Annex V :

MAIN GROUP 2 : Preservatives
=> Product Types related to leather applications :

PT 6 : Preservatives for products during storage *

PT 9 : Fibre, leather, rubber and polymerised materials preservatives

PT 11 : Preservatives for liquid-cooling and processing systems **

* Chemical products are sometimes treated with biocides
** Soaking biocides may be considered treatment of the process water
Biocidal Products Directive BPD 98/8/EC

Review Program existing active substances & biocides => placed on the market before 14 May 2000

BPD dossiers for Leather submitted by October 2008

New active substances & biocides => placed on the market from 14 May 2000
Biocidal Products Directive BPD 98/8/EC

Biocidal Products Regulation – BPR 528/2012/EC
Biocidal Products Regulation – BPR 528/2012/EC

Entry into force: 17th of July 2012
Implementation as of 1st of September 2013
Biocidal Products Regulation – BPR 528/2012/EC

- **Regulation**: immediately enters into force in all Member States (↔ Directive)
- Maintains **2-tier authorisation process**: Active substance + Biocidal Products
- Review program of existing active biocides continues under BPR!
- BPR authorisations mainly for wood preservatives & rodenticides

⇒ **Review program is running late**
**Extended until 2024!**
Important Difference between the BPR and the former BPD

- **Nominative Listing** of official applicants, incl. participants under Review Program (known as **Art 95 BPR List**) = list of “official sources” of active substances to be used only

As of **September 1, 2015**, a biocidal product can only be used if **sources of active substances are listed**

→ end of free-rider concept
Biocidal Products Regulation – BPR 528/2012/EC

L’Agenzia

Regolamenti

Trattamento delle sostanze chimiche problematiche

Informazioni sulle sostanze chimiche

Le sostanze chimiche nella vostra vita

Assistenza

ECHA > Informazioni sulle sostanze chimiche > Fornitori del principio attivo

Fornitori del principio attivo

L’ECHA è responsabile della pubblicazione dell’elenco delle sostanze interessate e dei rispettivi fornitori della sostanza e del prodotto, in conformità all’articolo 95 del regolamento sui biocidi (BPR), come modificato dal regolamento (UE) n. 334/2014 dell’11 marzo 2014. Lo scopo di tale elenco è “garantire un trattamento equo dei soggetti che immettono sul mercato principi attivi” (considerando 8 del regolamento sui biocidi).

I fornitori inclusi nell’elenco di cui all’articolo 95 comprendono i partecipanti al programma di riesame, i sostenitori di un principio attivo nuovo che hanno trasmesso un fascicolo ai sensi dell’articolo 11 della direttiva sui biocidi, BPD (direttiva 98/8/CE) o ai sensi dell’articolo 7 del BPR, i soggetti che hanno presentato domande di autorizzazione del prodotto laddove la domanda include un fascicolo alternativo del principio attivo (il cosiddetto ‘fascicolo di terza parte’) e i fornitori che hanno presentato una domanda a norma dell’articolo 95, paragrafo 1, del BPR e che è stata ritenuta conforme dall’ECHA.

L’elenco sarà aggiornato regolarmente dall’ECHA. A decorrere dal 1° settembre 2015 i biocidi non possono essere messi a disposizione sul mercato UE, a meno che il fornitore della sostanza o del prodotto sia iscritto nell’elenco di cui all’articolo 95 per il tipo di prodotto a cui il prodotto appartiene.

Le informazioni contenute nell’elenco sono accurate, per quanto è a conoscenza dell’ECHA. Se desiderate inviare un commento o delle richieste di modifica dell’elenco, potete presentare la richiesta di correzioni delle voci dell’elenco di cui all’articolo 95. Si segnala che i tempi necessari per prendere in considerazione la domanda possono variare in base alla complessità della richiesta di modifica.

See also

- Requests for corrections
- Article 95 LoA template [DOC][EN]
- Approval of active substances suppliers
- Q&A on Active substances suppliers

Download the list of active substances and suppliers [PDF][EN] 27 July 2016
Example of list using TCMTB as reference:

<table>
<thead>
<tr>
<th>Active Substance Name</th>
<th>EC number</th>
<th>CAS number</th>
<th>PT</th>
<th>Entity Name</th>
<th>Country</th>
<th>Supplier Type</th>
<th>Inclusion Reason</th>
<th>Inclusion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>(benzothiazol-2-ylthio)methyl thiocyanate (TCMTB)</td>
<td>244-445-0</td>
<td>21564-17-0</td>
<td>9</td>
<td>nv Buckman Laboratories</td>
<td>Belgium</td>
<td>Substance Supplier</td>
<td>RP Participant</td>
<td>24-Sep-14</td>
</tr>
</tbody>
</table>

https://echa.europa.eu/information-on-chemicals/active-substance-suppliers

• You can obtain information on the active substances, the Product Type (PT), and nominative suppliers from the ECHA website.

• Ensure that the biocides you are using are listed under the correct PT (e.g. PT 9), AND that the correct use application is covered.

• You should also obtain a compliance letter from your supplier.
We XXX, confirm that the biocidal product XXX is in compliance with the European Biocidal Products Regulation 528/2012/EC concerning the making available on the market and use of biocidal products. Furthermore, the active substance (benzothiazol-2-ylthio)methyl thiocyanate (CAS: 21564-17-0; EINECS: 244-445-0) is listed on Annex II of Commission Delegated Regulation (EC) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council for the following Product Types:
- 9 : Fibre, leather, rubber and polymerized materials preservatives
...
Furthermore, we also confirm the above mentioned active substance is listed on the Art. 95 list published on the ECHA website.
**Important Difference between the BPR and the former BPD**

Introduction of **new** concepts:

**Treated Articles**

*means any substance, mixture or article which has been *treated with,* or *intentionally incorporates* one or more biocidal products* (Definition - Art 3.1(I)-BPR)*
Treated Articles Provision

- **Leather articles cannot** be placed on the EU market **unless** treated with biocidal products containing active substances on the **Art 95 BPR List**

**Impact on leather industry:**
Affects imports of wet blue, finished leather and leather articles into Europe, where the leather was treated **outside of the EU**
Biocides used in treated articles that were available on the EU market on September 1, 2013, can remain on market until EU decision on Active Substance is completed:

- where the article (e.g. leather) is treated with a biocide, and
- if application/dossier was submitted at latest by September 1, 2016

Example for leather industry:

Fungicide CHED

BPR dossier submitted by Buckman to Norway (Rapporteur Member State)
BPR and REACH

- BPR is similar to REACH in concept, but was enacted earlier and has higher standards for substance review
- For commercial biocide Products, REACH also applies in that the solvents, emulsifiers, etc. need to comply with REACH

**REACH - Timeline for Chemicals**

- **Priority 1**: Chemicals > 1000 tons; CMR’s (> 1 ton)
  - Very toxic to aquatic organisms (> 100 tons)
  - May 2013

- **Priority 2**: Chemicals 100 - 1000 tons
  - Nov 2010

- **Priority 3**: Chemicals 1 - 100 tons
  - Non phase-in substances
  - Oct 2008

- **Non phase-in substances**: May 2018

**BPR - Timeline for Biocides**

- **Pre-registration**
  - May 2000
  - Oct 2008

- **Dossier submission**
  - Sept 2013
  - Sept 2015
  - Sept 2016

- **End of “Free Rider”**

- **End of Transition for New Actives**
  - • Treated Articles
  - • New Fungicides

- **BPR (528/12/EC) entry into force**

- **BPD (98/8/EC) entry into force**
SECTION B:

Government Regulations & Market Requirements

3. MARKET RESTRICTIONS ON BIOCIDES
Market Restrictions on Biocides

Governments control biocides because they have an obligation to protect the health of their people and the environment.

Who else seeks to restrict use of biocides?
- Brands and retailers
- Industry organizations
- Environmental organizations
- Activist groups

Why do NGO’s restrict biocides?
- Corporate risk
- Industry reputation
- Sharing of best practices / raise standards
- Concern for environment or consumers
Market Restrictions on Biocides

Approach to mitigate perceived risks represented by biocides is by restriction.

Use of RSL’s (Restricted Substances Lists) or an Ecolabel:

A. Biocide to be compliant with prevailing legislation (e.g. BPR) → No issues
B. Arbitrary limits on commonly used biocides → Some issues

Many NGO’s might have the best intentions, BUT:

– May not understand leather industry and its specific needs well
– May not have expertise in toxicology; might not use risk assessment approach; processes may not be well defined.
– Some limits are “cut-and-paste” from other industries or other ecolabels
– Limits can be secretive / competitive / open to interference
– Once in place, limits can be hard to change
– Unrealistic limits create unnecessary technical barriers to trade
Key Points:

• Leather is different to textiles - process sequence & material requirements vary significantly:
  - Natural, renewable
  - Three dimensional
  - Synthetic, oil origin
  - Two dimensional

• It is very rare that tanners overdose biocides:
  - Biocides (fungicides) are very expensive and market is highly competitive.
  - Almost all industry problems - too little active substance is present

• Difference in the amount of biocide (fungicide) needed:
  - Depends on raw material, process parameters, end product.
  - Level of nutrients (e.g. natural sugars & fats)
  - Level of contamination – e.g. fungal spores present
  - Ambient conditions – temperature
  - Technical issues related to analytical method and expression of results
Market Restrictions on Biocides

Some specific examples of NGO imposed limits on industry:

- **Ecolabels:**
  - EU Ecolabel for footwear – to meet EU BPR requirements
  - German Blue Angel - specifies major fungicides with workable limits
  - Oeko-Tex Leather Standard – major fungicides with workable limits
  - Bluesign – Unworkable limits on OPP and OIT

- **Industry Organizations:**
  - GADSL – to meet EU BPR requirements
  - CADS / DSI - specifies all major fungicides with workable limits

- **RSL’s:**
  - AFIRM – Specifies OPP but with workable limits
  - Individual brands – some significant differences, most limits are workable

**BEST PRACTICE:** Biocides should be used in accordance with EU BPR requirements. This represents the highest standard for comprehensive review using scientific Risk Assessment approach.
Evolution of RSL’s

Over the last decade or so, there has been a lot of activity among NGO’s to develop RSL’s - some of these include limits on biocides.

**Good news!**

Most of the more restrictive limits on commonly used fungicides have been raised over the last few years to more workable limits.

**But:** biocides remain under review by some brands.

**Be Pro-active:** There is a need for the industry to continue to advocate against limits that are not scientific or are too restrictive for practical tannery operations.
Best Practice for Tanners

1. Work with a good Supplier
   One that has the products, processes, and knowledge to ensure performance

2. Optimize your applications
   Based on your specific raw materials, processes, and preservation requirements

3. Document Biocide Compliance with BPR
   Ensure the active substances applied are supported under the BPR - specifically the appropriate Product Type and for the intended use (EU No.528/2012 - Art 95 List). Request Documentation.

So, what do I need to do?
Best Practice for Tanners

4. Confirm Compliance for imported articles
   Confirm that wetblue, crust or finished leather, if intentionally treated with a biocide, complies with BPR Art. 95 Treated Article provision. Document.

5. Determine customer RSL requirements
   Determine if there are any restrictions on presence of biocide residuals in leather articles sourced by your customer.

6. Pro-actively engage on biocide restrictions
   Work with your biocide supplier and industry organizations if RSL limits on the existing biocides are too restrictive or not workable.

So, what do I need to do?
**Topics Covered**

**SECTION A:**

**Microorganisms and their Control in Leather Industry**

1. Microorganism problems in leather production
2. Best practices in control of microorganisms
3. Importance of monitoring

**SECTION B:**

**Government Regulations & Market Requirements**

1. Risk assessment
2. Government regulations on biocides
3. Market restrictions on biocides

**SECTION C:**

**Questions and General Discussion**
Seminar on Microorganism Control

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Thank You!